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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,055	03/26/2004	John B. Cline	1626-309	7598

25881 7590 11/24/2006

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/811,055

Applicant(s)

CLINE, JOHN B.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-58 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 35-58 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/430,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '542 application claims every material limitation of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

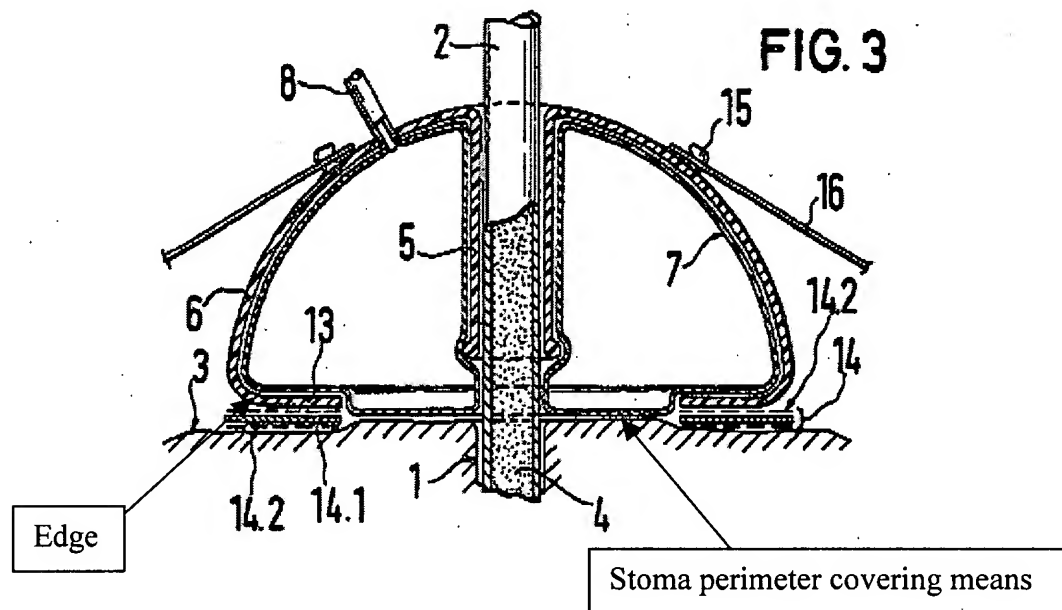
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39, 46 and 51 are rejected under 35 U.S.C. § 102(b) as being anticipated by Weigand (US 4,096,853).

Regarding claim 35, Weigand teaches an ostomy device capable of sealing a stoma (1) said device comprising recess defining means (6); means (14, 15, 16) for securing said recess defining means (6) to the body (3) proximate the stoma (1); and stoma perimeter covering means, situated externally to the body (3), over the stoma perimeter (1), within said recess

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defining means (6), said recess defining means (6) defining, with said stoma covering means, a chamber capable of being pressurized via conduct (8) to press said stoma perimeter covering means against the stoma perimeter (1)(col. 3, lines 6-20)(see annotated figure 3, infra).



Regarding the functional limitations, apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114. If the prior art discloses structure that can function according to the limitations of the claims, then the prior art meets the claims.

Regarding claim 36, Weigand teaches that the stoma perimeter covering means comprises a flexible member (7)(col. 3, lines 6-20).

Regarding claim 37, Weigand teaches a stoma perimeter covering means having an edge fixed to the interior of said recess-defining means (6)(see figure 3).

Regarding claim 38, Weigand teaches a means (8) for pressurizing the chamber (col. 3, lines 6-20).

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Regarding claim 39, Weigand teaches that the pressurizing means (8) comprises means (8) in said recess defining means (6) for permitting entrance of fluid into said chamber (col. 3, lines 6-20).

Regarding claim 46, Weigand teaches a pump (col. 3, lines 32-39).

Regarding claims 50 and 51, Weigand teaches removable means (14) for engaging and adhering the recess defining means (6) to tissue (3) surrounding a stoma (1)(col. 3, lines 32-39).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Weigand.

Weigand does not disclose expressly that the pump means is integral.

Merely making what is known in the art to be separable, integral is not sufficient to patentably distinguish the claimed invention over the prior art. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

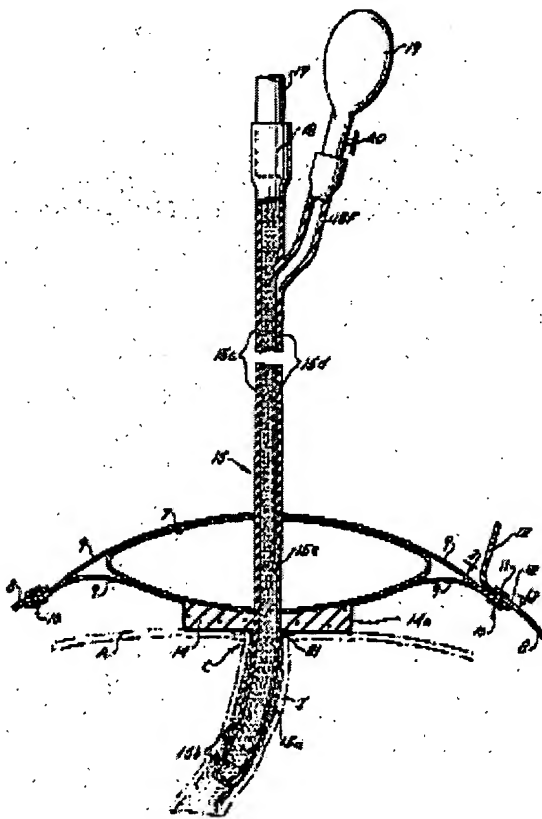
Claims 42, 44, 45 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weigand as applied to claims 35-39, 46 and 51 above, and further in view of Lepar (US 3,543,744).

Weigand does not disclose expressly a flexible pressurizing means or a valve.

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Lepar teaches a flexible hand pump (19) and a valve (20) for applying and maintaining pressure in the bladder (7)(see fig. 2, infra).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to add the hand pump and valve of Lepar to the device of Weigand in order to provide a means known in the art to apply and maintain pressure in Weigand's bladder.



Regarding claims 44 and 45, Lepar teaches a valve (20) which can limit or release pressure.

Regarding claim 47, Lepar teaches a valve (20) that can be used to vent the device.

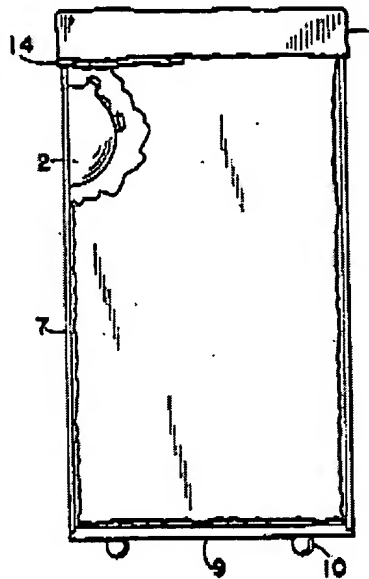
Claims 52, 53, 55 and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weigand as applied to claims 35-39, 46 and 51 above, and further in view of Cornwell (US 5,195,635 A).

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Weigand does not disclose expressly that the device can be used with a collection pouch.

Cornwell teaches an elongated, collapsible pouch (1) for disposing of infectious medical wastes (see fig. 5, *infra*).

**FIG. 5**



At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the medical waste pouch of Cornwell to dispose of the device of Weigand in order to provide a means of safely disposing of the device after use.

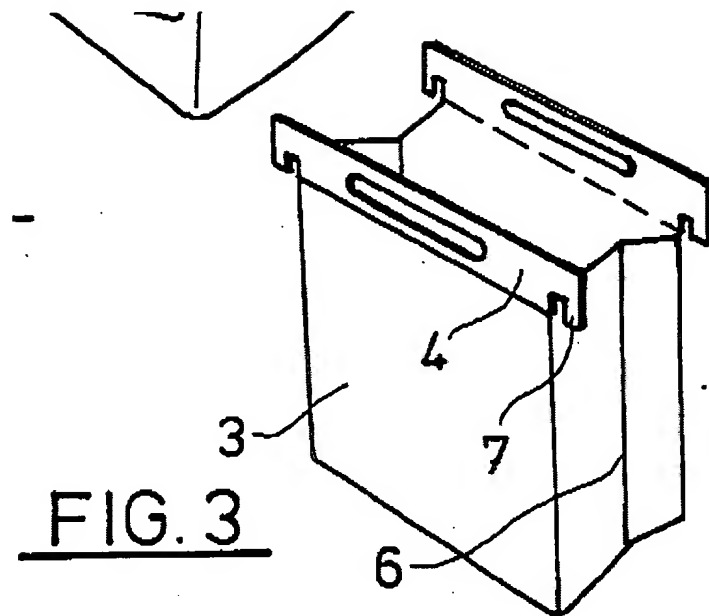
Claims 52 and 56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weigand as applied to claims 35-39, 46 and 51 above, and further in view of Bergmann *et al.* (DE 43 40 705 A1; hereinafter: "Bergmann").

Weigand does not disclose expressly that the device can be used with waste collection means having a concertina-like configuration.

Bergmann teaches a waste bag (4) having a concertina configuration (see English language abstract)(see fig. 3, *infra*).



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At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the medical waste pouch of Bergmann to dispose of the device of Weigand in order to provide a means of conveniently disposing of the device after use.

Claims 40 and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weigand as applied to claims 35-39, 46 and 51 above, and further in view of Jackson (US 4,429,856).

Weigand does not teach a one-way valve.

Jackson teaches a one-way inflation valve that permits an inflated device to remain inflated.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to add the check valve of Jackson to the device of Weigand in order to provide a means of keeping the bladder inflated.

***Response to Arguments***

Applicant's arguments with respect to claims 35-58 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Bogart  
15 November 2006

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

